AF/1654 #

Inv

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Yuan-Tsong Chen		
Application No.:	09/902,461	Group:	1654
Filed:	July 10, 2001	Examiner:	M. Meller
Confirmation No.:	6796		
For:	TREATMENT OF GLYCOGEN STORAGE DISEASE TYPE II		

CERTIFICATE OF MAILING

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REPLY BRIEF

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Sir:

This Reply Brief is submitted in response to the Examiner's Answer mailed from the U.S. Patent and Trademark Office on April 7, 2004. The issues are addressed in the order in which they were raised in the Examiner's Answer.

Issue 1: Rejection of Claims 1-9 and 11-23 under 35 U.S.C. §112, Second Paragraph

The Examiner has maintained the rejection of Claims 1-9 and 11-23 under 35 U.S.C. §112, Second Paragraph, stating that "periodically" is vague and indefinite.[1]

Despite the Examiner's contention, administering the enzyme "periodically at an administration interval" fully complies with Section 112, Second Paragraph. As pointed out in

[1]Claim 22 does not use the word "periodically" so the rejection of this claim on this ground should be reversed automatically.

Appellant's Brief, the fact that this phrase does particularly point out and distinctly claim the administration regimen for human acid α-glucosidase (GAA) is supported by: (1) the teachings in Appellant's specification; (2) the dictionary definition of "periodically;" and (3) the fact that the term has been previously allowed in U.S. patent claims.

In answer to the Examiner's question, administration of GAA every hour, every week or every month are all examples of administering the enzyme "periodically at an administration interval." See Appellant's Specification, e.g., Page 3, lines 2-4.

In response to Appellant's arguments, the Examiner has attempted to turn the definition of "periodically" into "frequently" by focusing on only a portion of the second dictionary definition. This is a misapplication of the law relating to use the use of dictionary definitions. The intrinsic evidence (e.g., Appellant's specification) clearly points to the first dictionary definition, i.e., "at regular intervals." For example, as explained in Novartis Pharms. Corp. v. Eon Labs Mfg., 2004 U.S. App. LEXIS 6390, *11-12 (Fed. Cir. 2004):

> For more than 45 years we, and our predecessor court, have looked to the intrinsic record to determine as a matter of claim interpretation which of the available, relevant definitions should be applied to the claim term at issue. As our predecessor court explained, "one need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the word is used in a given claim. The subject matter, the context, etc., will more often than not lead to the correct conclusion." [citations omitted].

This position is further supported in International Rectifier Corp. v. Samsung Electronics Co., 361 F.3d 1355, 1369-70 (Fed. Cir. 2004) in which the Court stated "The specification must be examined in every case to determine which of the possible dictionary meanings is consistent with the use of the claim term in the context of the claims and the written description...." [citations omitted].

The correct definition for "periodically" is the first dictionary definition, namely, "at regular intervals of time." This is clear from Appellant's specification, as noted above.

One of ordinary skill in the art would have no difficulty in determining whether GAA was being administered to a patient afflicted with Pompe's Disease "periodically." As such, Claims 1-9, 11-21 and 23 comply with 35 U.S.C. §112, Second Paragraph. See, e.g., In re Warmerdam, 33 F.3d 1354, 31 U.S.P.Q. 2d 1754, 1759-60 (Fed. Cir. 1994).

Issue 2: Rejection of Claims 1-4, 9, 21 and 23 under 35 U.S.C. 102(b) over Fuller *et al.*

The Examiner has also maintained the rejection of Claims 1-4, 9, 21 and 23 under 35 U.S.C. §102(b) as being anticipated by Fuller *et al.*, Reference AV2.

Fuller *et al.* do not describe, expressly or inherently: (1) administration of GAA to a human individual; (2) administration of GAA periodically at an administration interval; or (3) treatment of glycogen storage disease type II (GSD-II) (Pompe's Disease) in a human individual. Since these are all elements of Appellant's claims, Fuller *et al.* do not anticipate these claims. See, e.g., Motorola, Inc. v. Interdigital Technology Corp., 121 F.3d. 1461, 1473, 43 U.S.P.Q. 2d 1481, 1490 (Fed. Cir. 1997).

Issue 3: Rejection of Claims 1-7, 11-18, 21 and 23 under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a), over Fuller *et al.*

The Examiner has also maintained the rejections of Claims 1-7, 11-18, 21 and 23 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over, Fuller *et al.*

The discussion above regarding lack of anticipation by Fuller *et al.* applies with even greater force here because the additional claims rejected by the Examiner here present even more limitations "missing" from the teachings of Fuller *et al.* For example, in addition to the missing limitations described above, Fuller *et al.* also fail to teach at least (1) the specific dosages recited in Claims 5-7, (2) the specific administration intervals recited in Claims 11-15, and (3) the specific administration methods recited in Claims 16-18.

In regard to the rejection under § 103(a), as pointed out in Appellant's Brief, Fuller *et al.* do not provide a suggestion to try periodic administration of GAA produced in CHO cells to a human afflicted with Pompe's Disease, the specific dosages (Claims 5-7), the administration intervals (Claims 11-16), the specific administration methods (Claims 16-19) nor the combination of GAA with an immune suppressant (Claims 19-20).

In addition, Fuller *et al.* fail to teach any reasonable basis for an expectation of success in treating humans afflicted with Pompe's Disease, a long known and terrible disease for which all

known previous treatments failed, including enzyme replacement therapy. See Appellant's Brief, Pages 7-8. As stated in Boehrenger Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1354, 65 U.S. P.Q. 2d 1961, 1972 (Fed. Cir. 2003), "...there can be little better evidence negating an expectation of success than actual reports of failure."

Issue 4: Rejection of Claims 1-9 and 11-23 under 35 U.S.C. §103(a) over Bijvoet *et al.* in view of Fuller *et al.*

The Examiner has also maintained the rejection of Claims 1-9 and 11-23 under 35 U.S.C. §103(a) as being obvious over Bijvoet *et al.* in view of Fuller *et al.*

There is nothing in the Bijvoet *et al.* or Fuller *et al.* references that would suggest their combination to a person skilled in the art. In fact, Bijvoet *et al.* teach the undesirability of using GAA produced in CHO cells, the very subject of Fuller *et al.*, and suggest that it be produced in the milk of transgenic animals, such as mice.

In attempting to justify this rejection, the Examiner has made two allegations on page 6 of the Examiner's Answer. The first is that it would be obvious to use an immunosuppressant in combination with GAA, as required by Claims 19 and 20. Secondly, the Examiner has alleged that determining the administration regimen is "...merely a matter of judicious selection and routine optimization." There is no basis in either the Bijvoet *et al.* reference or the Fuller *et al.* reference for either of these allegations. They are simply naked allegations by the Examiner, totally unsupported by any teachings in the references.

Appellant is unsure exactly how the teachings from the Bijvoet *et al.* and Fuller *et al.* references could be combined. Nevertheless, what is clear is that, under any attempted combination, there is still no teaching of administration of GAA to a human being, no teaching of periodic administration of GAA, and no teaching of a treatment of a human being having Pompe's Disease. This shows the fallacy of concluding that Appellant's claimed invention would be obvious in view of the combined teachings of these references. Even a hindsight reconstruction from these references does not produce Appellant's invention.

The rejected claims are not rendered legally obvious by Bijvoet *et al.* in light of Fuller *et al.* for at least three reasons: (1) there is no suggestion to a person of ordinary skill in the

relevant art to combine these references, (2) there is no reasonable expectation that such combination would successfully yield the claimed invention, and (3) even together these two references fail to literally teach each and every limitation of the rejected claims, either expressly or inherently. *See, e.g.,* MPEP 2143 (to establish obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings," "there much be a reasonable expectation of success," and "the prior art reference (or references when combined) must teach or suggest all the claim limitations".

Issue 5: Rejection of Claims 1-9 and 11-23 under 35 U.S.C. 103(a) over Fuller *et al.*

The Examiner has also maintained the rejection of Claims 1-9 and 11-23 under 35 U.S.C. 103(a) over Fuller *et al.* The comments set forth above in regard to the § 103(a) portion of Issue 3 also apply to this rejection.

CONCLUSION

For the reasons presented above and in Appellant's Brief On Appeal, Appellant respectfully requests the Board of Patent Appeals and Interferences to reverse all of the rejections currently maintained by the Examiner in the above-identified application.

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By David E. Brook

David E. Brook
Registration No. 22,592
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Date: 6/7/04